

Guidance Documents Pertinent to OTRR Products
Product Issues

- 1996: FDA Guidance Concerning Demonstration of Comparability of Therapeutic Biotechnology-derived Products (a new ICH topic)
- 1996: Guidance for Industry for the Submission of CMC Information for a Therapeutic Recombinant DNA-Derived Product
- 1997: Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use update – addressing testing requirements, dosimetry, clinical development, etc.
- 1998: ICH Guidance on quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production...(Q5-D)
- 1998: ICH Guidance on Viral Safety Evaluation of Biotechnology products Derived From Cell Lines of Human or Animal Origin (Q5-A)
- 1999: ICH Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products (Q6B)
- 1999: Draft Guidance on Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations

Selected Clinical Guidance Efforts – General
(CBER /CDER)

- 1998: Fast Track Drug Development Programs – Designation, Development, and Application Review.
- 1999: Clinical Development Programs for Drugs, Devices and Biological Products for the Treatment of Rheumatoid Arthritis (RA)
- 2000: Chronic Cutaneous Ulcer and Burn Wounds – Developing Products for Treatment

- 2000: Draft Guidance on Developing Medical Imaging Drugs and Biological Products
- 2000: Various Draft Product labeling guidance (e.g., adverse reactions draft 2000, clinical studies draft 2001)
- 2001: Draft Guidance for Clinical Trial Sponsors On the Establishment and Operation of Clinical Trial Data Monitoring Committees
- 2001: Draft Guidance on Reports on the Status of Postmarketing Studies - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997

Web Addresses

CDER website –

<http://www.fda.gov/cder/>

CDER guidances –

<http://www.fda.gov/cder/guidelines.htm>

CDER therapeutics –

<http://www.fda.gov/cder/therapies.htm>